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Dr. Irwin Butensky  
Playtex Products, Inc.  
75 Commerce Drive  
Allendale, New Jersey 07401

Dear Dr. Butensky:

Thank you very much for forwarding on the manual for the standardization of colposcopy for the evaluation of vaginally administered products, from the World Health Organization. At this time, practicing gynecologists primarily use colposcopy to evaluate patients with abnormal pap smears. The vast majority of these patients have cervical abnormalities, and gynecologists usually glance at the vaginal mucosa, but certainly do not complete forms anywhere near as extensive as those suggested in the manual. If we do see pathology, we complete the appropriate biopsies, noting the site of any abnormality.

Vaginal ulcerations have been noted for years. They can be seen in women who wear tampons, and those who do not. They almost always clear spontaneously, and have not been associated with any significant pathological conditions, including toxic shock syndrome. I do not know what the WHO is hoping to accomplish by demonstrating any particular abnormalities, as these abnormalities are not known to be correlated to any patient illnesses.

The protocol that they outline would be very time consuming, for both the practitioner, and even more importantly, for the patient, who would have to spend this time with a large speculum in her vagina, which would be very uncomfortable. I would imagine this would discourage participation in clinical trials, if such a protocol had to be performed on her regularly. My patients certainly do not enjoy the time that even a standard colposcopy for cervical evaluation requires.

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,  
*Mary Jane Minkin, M.D.*  
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